

CONTRACT LABORATORY INSPECTION

Inspection Report of the _____ Laboratory for Provisional Approval to Perform PPQ Diagnostic Tests for *P. ramorum*

Date:

Laboratory:

Inspected By:

	Examined Y/N	Compliant Yes/No/NA	Supporting Documents	Comments/Concerns
I. General Information				
A. Personnel - contact name/title				
B. Lab Layout on File				
C. Bios of Accountable Officials				
D. Equipment List				
Brief Description of Lab Environment:				
II. Receipt				
A. SOP for delivery and notification of AO				
B. Temporary Storage before log-in				
III. Log-In				
A. Room for log-in				
B. Personnel				
C. Are procedures adequate to insure sample integrity?				
D. Log-in system				
1. Form 391				
2. File setup and storage				
E. Storage of samples				
IV. Sub-Sampling				
A. Personnel				
B. Sampling room and ventilation				

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	Examined Y/N	Compliant Yes/No/NA	Supporting Documents	Comments/Concerns
C. Pre- and Post-sample sanitation (UV, bleach solution, etc.)				
D. Flame source				
E. Disposables (gloves, kimwipes, sample containers, etc.)				
F. Lab wear (Lab coat, etc)				
G. Handling equipment and procedure (forceps, scaplel, etc)				
H. Written procedures for tracking and handling samples?				
I. Are procedures adequate to insure sample integrity?				
J. Sample Process				
V. ELISA				
A. Personnel - contact name/title				
B. Training/Training Records				
C. Knowledge of procedures				
D. Tissue masceration/preparation				
E. Agdia kit/Written procedures				
F. ELISA plate reader				
G. Written and electronic records				
VI. DNA Extraction				
A. Personnel -- contact name/title				
B. Training/Training Records				
C. Knowledge of procedures				
D. Qiagen kit and/or writtem procedures, with review of deviations or modifications				
E. Equipment maintenance				
F. Overall cleanliness of laboratory work area				

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	Examined Y/N	Compliant Yes/No/NA	Supporting Documents	Comments/Concerns
G. Extra reagents and equipment				
1. Liquid Nitrogen				
2. Dedicated pipettes				
3. Ice machine				
4. Beat beater or tissue mascerator				
5. Lab coats				
H. Disposables				
1. Gloves				
2. Barrier pipette tips, microcentrifuge tubes				
3. Reagent grade ethanol				
VII. Real-Time PCR				
A. Personnel - contact name/title				
B. Training/Training Records				
C. Knowledge of procedures				
D. Written procedures				
E. Reagents				
1. Polymerase used				
2. Primers				
3. Probes				
4. Validation of controls				
F. Equipment				
1. Sequence Detector				
2. Dedicated micropipettes				

CONTRACT LABORATORY INSPECTION

	Examined Y/N	Compliant Yes/No/NA	Supporting Documents	Comments/Concerns
3. Sticky floor mats in key locations				
G. Other				
VIII. Nested PCR				
A. Personnel - contact name/title				
B. Training/Training Records				
C. Knowledge of procedures				
D. Written procedures				
E. Reagents				
1. Platinum Taq (500 U)				
2. Primers, 3 sets (Phyto 1/4, Phyto 2/3, NS1/NS2)				
3. Validation of controls				
F. Equipment				
1. Thermocycler				
2. Dedicated micropipettes				
3. Sticky floor mats in key locations				
G. Other				
IX. Gel Electrophoresis and Documentation				
A. Location				
B. Type of Gel Electrophoresis unit (capacity)				
C. Power Supply (quantity and/or back ups, timing)				
D. Agarose percentage				
E. Staining Procedure destaining?				
F. Gel Documentation system				

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	Examined Y/N	Compliant Yes/No/NA	Supporting Documents	Comments/Concerns
written and/or electronic records				
X. Laboratory Equipment/Environment				
A. Maintenance Schedules				
B. Performance Checks				
C. Cleaning/Changing of Reagents				
D. Cleaning of work areas				
E. Water quality monitoring				
F. Temperature/humidity checks				
G. Pipette calibration checks				
H. Monitor freezer/refrigerator temperatures				
XI. Interpretation				
A. Personnel - contact name/title				
B. Training/Training Records				
C. Understanding of procedures				
D. Written procedures				
E. QA/QC				
1. Internal/In house review/Sample rejection criteria				
a. Knowledge of procedures				
b. Written procedures				
2. External (Understanding USDA procedures/ Criteria				
XII. Reporting				
A. Personnel - contact name/title				
B. Training/Training Records				

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C. Understanding reporting chain of command - USDA vs. local				
D. Written procedures				
E. Recognition of non-conforming work				
XIII. Understanding of USDA Expectations/Procedures				
A. Discussion				
B. Reagent purchasing procedures				
C. Billing procedures				
D. Names of contact person(s) for the above				

Note: How to read this checklist.

Yes in 'Compliant' Column – lab is fully compliant on the specific requirement stated in that row.

No in 'Compliant' Column – lab has refused or is unable to be compliant on the specific requirement stated in that row.

Yes in 'Examined' Column – lab has been examined on the specific requirement stated in that row and:

1) a recommendation has been made to achieve and/or maintain full compliance.

Or

2) a condition or document needed for compliance needs to be completed.

No in 'Examined' Column – lab did not have requirement available for view at time of visit.

If both Columns are empty – This requirement is not applicable for the lab and/or process used by the lab for this diagnostic.